

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
 (Chapter II of the Patent Cooperation Treaty)  
 (PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference<br>12432490/EJH/DYS  | <b>FOR FURTHER ACTION</b>                                  | See Form PCT/IPEA/416                          |
| International application No.<br><b>PCT/AU2004/000427</b>  | International filing date (day/month/year)<br>2 April 2004 | Priority date (day/month/year)<br>3 April 2003 |
| International Patent Classification (IPC) or national classification and IPC<br><br>Int. Cl. <sup>7</sup> A61K 31/47, 31/473; A61P 25/28, 39/04, 39/06 |  |  |
| Applicant<br><br>PRANA BIOTECHNOLOGY LTD et al   |  |  |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☒ (sent to the applicant and to the International Bureau) a total of 28 sheets, as follows:
- ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

|   |  |
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| Date of submission of the demand<br>23 December 2004  | Date of completion of the report<br>11 July 2005                         |
| Name and mailing address of the IPEA/AU<br><br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br><b>S. Chew</b><br>Telephone No. (02) 6283 2248 |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000427

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1 (b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-65 as originally filed/furnished
  - pages\* received by this Authority on with the letter of
  - pages\* received by this Authority on with the letter of
- ☒ the claims:
- pages as originally filed/furnished
  - pages\* as amended (together with any statement) under Article 19
  - pages\* 66-93 received by this Authority on 23 December 2004 with the letter of 23 December 2004
  - pages\* received by this Authority on with the letter of
- ☒ the drawings:
- pages 1/3-3/3 as originally filed/furnished
  - pages\* received by this Authority on with the letter of
  - pages\* received by this Authority on with the letter of
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/AU2004/000427

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Claims      | YES |
|                               | Claims 1-39 | NO  |
| Inventive step (IS)           | Claims      | YES |
|                               | Claims 1-39 | NO  |
| Industrial applicability (IA) | Claims 1-39 | YES |
|                               | Claims      | NO  |

## 2. Citations and explanations (Rule 70.7)

This report has considered the following documents cited in the International Search Report:

D1 WO 2002/051415

D2 US 6001852

NOVELTY (N): Claims 1-39

D1 discloses the use of clioquinol and phanquinone in treating or preventing prion disorders eg Creutzfeld-Jacob disease and spongiform encephalopathies. It further discloses a list of 8-substituted quinolines (See page 18 line 21 to page 20 line 11) suitable for use in the treatment.

D2 discloses a method for treating or preventing Alzheimer's Disease (AD), a neurological disease resulting from oxidative stress, with clioquinol and optional with vitamin B12. It is also disclosed that the method of the invention prevents or alleviates the signs and symptoms of AD eg cognitive impairment and memory loss (See col. 6 lines 43-48, col. 7 lines 18-31 and claims 1, 3 and 4).

Claims 1, 2 and 16-22 defining the use of any 8-substituted quinolone or an agent which reduces the levels of reactive oxygen species (as in claim 21) in the treatment of a neurological condition or disorder, are anticipated by the disclosures of clioquinol in D1 and D2.

Claims 3-15 and 23-39 are also not novel in the light of the disclosure of D1 which teaches several suitable 8-substituted quinolines which fall within the scope of the compounds envisaged by the claims.

Therefore claims 1-39 lack novelty.

INVENTIVE STEP (IS): Claims 1-39

As above.

INDUSTRIAL APPLICABILITY (IA): Claims 1-39

Claims 1-39 have industrial applicability.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000427

## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 20 are not clear with regard to the terms "derivative", "homolog", "analog", "chemical equivalent" and "mimetic". It is not clear what compounds are being envisaged by these broad terms.

Claim 5 is not clear as it is appended to itself.